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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,149	08/08/2003	Gerald E. McDonnell	STRSP0119US	3426

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EXAMINER

HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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12/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/637,149

Applicant(s)

MCDONNELL ET AL.

Examiner

MICHELLE HORNING

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 January 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1 and 31-75.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/M. H./
Examiner, Art Unit 1648

/BO PENG/
Primary Examiner, Art Unit 1648

Continuation of 11. does NOT place the application in condition for allowance because:

In response to the rejection under 35 USC 112, 1st paragraph (scope of enablement), Applicant provides multiple US Patents, including US Patent Nos. 707152, 7129080, 7217685, 7393818 and 7803315, as support for the claimed invention being fully enabled. It is noted that the patents are not within the scope of the claimed subject matter and the patents do not provide any correlation between IFDO and prion proteins, such that the methods/conditions that would successfully inactivate IFDO would also successfully inactivate prions. It is noted here that the '080 patent provides "correlation studies" in order to establish a correlation between the response of test proteins with that of prions using methods/conditions KNOWN to be effective against prions (col. 11, Example 3). This correlation is not bidirectional and fails to establish that successful methods/conditions known to inactivate IFDO would also inactivate prions.

Applicant points to a recitation found in the Burdon reference (1996) for additional support of using IFDO as a prion model. However, this recitation is incomplete and fails to represent the teaching of the reference as a whole. Briefly, Burdon describes that IFDO utilizes lipoproteins for replication and compares this to TSE agents which uses apolipoprotein E (p. 14, col. 1). However, there is no teaching that supports using IFDO as a model for prion inactivation.

Applicant further points to Dyas (1990) for support of using IFDO as a prion model. Although Applicant did not provide the reference, the abstract merely makes the suggestion that IFDO can be used as a model for sterilization of items contaminated with CJA. Note that the abstract only describes various conditions for inactivating IFDO but not for the inactivation of prion proteins.

Applicant contends that the present application and the cited commonly-owned patents have established a correlation between an IFDO and a prion. However, in view of the above discussion, this is not found to be persuasive.

In response to the rejection under 35 USC 103, Applicant contends that the examples of the instant specification show an unexpected synergistic effect that overcomes any prima facie case. This argument is not clear, given such synergetic effects are not relevant to inactivation of prion proteins and are only shown to occur in inactivating IFDO.

Applicant notes that claim 45 is directed to (in part) using at least one phenol with a Log Pc value of at least about 2.5 and points to Example 3 for correlating the partition coefficients with the results in log IFDO reduction. Applicant contends that there is no evidence that support that it would have been obvious to do what is claimed in claim 45. Note that the instant specification provides Log Pc values for various phenols, including for those found in the composition taught by Ernst and Race, such as, o-benzyl-p-chlorophenol. O-benzyl-p-chlorophenol has a Log Pc value of at least about 2.5 (Table 3 of the instant specification). A chemical and its properties are inseparable. Also see MPEP 2112.01 II. COMPOSITION CLAIMS-IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES.

No argument is found persuasive.